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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,471	10/23/2001	Eriko Takano	0380-P02329US1	5210
110	7590	12/16/2004	EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,471

Applicant(s)

TAKANO ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9,11,13,15 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9,11,13,15 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (mailed on March 19, 2004), Applicants filed a response and amendment received on June 24, 2004 and on September 24, 2004. Said amendment cancelled Claims 2-8, 10, 12, 14, 16-18, and 24-32 and amended Claims 15 and 19-23. Thus, Claims 1, 9, 11, 13, 15, and 19-23 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/242,561 filed on October 23, 2000.

Withdrawn - Objections to the Specification

3. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicant's amendment to the title.

4. Previous objection to the specification for a typographical error on page 32, line 3, is withdrawn by virtue of Applicant's amendment.

Maintained - Objections to the Specification

5. Previous objection to the specification for inappropriate notation of an internet address on page thirteen, line 9, is maintained. Applicant has amended the citation, but no date of retrieval is in the amendment. The date of retrieval is crucial in the understanding of the citation because

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the internet is not a “permanent” entity. See M.P.E.P. § 707.05(e) for the acceptable notation of an internet address.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

6. Previous rejections of Claims 19-23 under 35 U.S.C. § 112, second paragraph, as being indefinite for items (a) and (b) being the same and confusing and for the term “about” are withdrawn by virtue of Applicant’s cancellation of reference to EMBL AJ007731.

7. Previous rejection of Claims 20-23 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “the level of sequence identity” is withdrawn by virtue of Applicant’s amendment.

8. Previous rejection of Claims 15 and 19-23 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant’s amendment to the claims, now drawn to a method of screening.

Maintained - Claim Rejections - 35 U.S.C. § 112

9. Previous rejection of Claims 1, 9, 11, 13, 15, and 19-23 under 35 U.S.C. § 112, second paragraph, as being indefinite for the nature and/or structure of the *scbA* gene for deletion in *S. lividans* is maintained. Applicant’s arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant’s remarks at the top of page 13 indicate that the Examiner did not follow “the appropriate procedural approach”; however, no specifics are offered with respect to the case law cited prior.

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Applicant argues that the characterization of the *scbA* gene is not necessary but the claimed invention is one in which said gene is functionally deleted. Applicant further argues that one's ability to functionally delete the *scbA* gene has "nothing to do with the gene's characterization". The Examiner disagrees. Applicant even cites that the specification discloses deletion in *S. coelicolor* by using a mutant *scbA* gene from *S. coelicolor*. Thus, the nature of the *S. lividans* gene must be known to follow an analogous procedure in *S. lividans*. As previously noted,

"The specification describes the *scbA* gene of *S. coelicolor*. While the specification teaches deletion in *S. lividans* using an *scbA* deletion mutant allele from *S. coelicolor* (see page 29), no identification of an *scbA* gene in *S. lividans* is described. In view of the homologue names of *barX* (*S. virginiae*) and *afsA* (*S. griseus*), the nature and/or structure of the gene to be deleted in *S. lividans* are unclear without specific identification either in the specification or the art of an *scbA* gene per se. Clarification is required."

10. Previous rejection of Claims 15 and 19-23 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "homologue" is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the term cannot be considered indefinite in view of the specification on pages 11-12, which reads:

A gene of a *Streptomyces* species or strain, which gene is a "homologue" of or is "homologous" to the *scbA* gene of *S. coelicolor*, **may be** the gene which shows greatest deduced amino acid sequence identity to *scbA* of all genes of said species or strain; alternatively or additionally, it **may be** a gene which is capable of specific hybridisation with the amplification product obtained using the primers oligol ... and oligo2 ... to amplify total DNA of said species or strain ... ; alternatively or additionally, it **may be** a gene encoding a polypeptide having at least about 35% sequence identity with the deduced amino acid sequence of *scbA* as shown in Fig. 10, preferably at least about 40% (which is the homology found between *scbA* and other homologues of the *afsA* gene of *S. griseus*) more preferably about 50%, 60%, 65% (which is the homology found between *scbA* and *afsA* of *S. griseus*), 70%, 80%, 90%, or 95% (emphasis added)

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Thus, Applicant is arguing that what “may be” a homolog is a clear definition of homolog and should be interpreted into the claims from the specification as a real limitation. This is impermissible; although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, all of the features of homology noted in the specification on pages 11-12 (and quoted above) are structural, not functional. As previously noted, no description of a functional relationship between scbA and its homologues is noted in the specification or the claims; is one required, which is typical of homologues in the art? Clarification on these points is required and the rejection is maintained.

11. Previous rejection of Claims 1, 9, 11, 13, 15, and 19-23 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for deleting the scbA gene, does not reasonably provide enablement for *function* deletion of the scbA gene is maintained. Applicant’s arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that the Examiner has contended that the lack of enablement of the instant claims is at issue because all possible means of effecting functional deletion of the scbA gene have not been exemplified; this is not the case. As previously noted, the specification particularly describes functional deletion methods on page 9.

“In the specification on page 9, functional deletion is described to include any alteration, which effects normal expression of that gene. Within this definition is included the alteration of “the transcriptional and/or translational regulatory sites ... to prevent normal transcription and/or translation of the gene.”

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The Examiner further goes on to extend a Wands analysis citing the lack of examples in the specification, lack of direction, nature of the invention, and low predictability of the full scope of the invention. While it is true that not every means for effecting functional deletion need be exemplified in the specification, those that are not expressly exemplified must not require undue experimentation to achieve. As clearly set forth by the Wands analysis, means of functional deletion other than actual gene deletion, means which are specifically prescribed to be included in the claimed invention by the specification's description, are not enabled. Thus, the instant claims are not enabled to the full extent of their scope.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

12. Previous rejection of Claims 15 and 19-23 under 35 U.S.C. § 102(a) as being anticipated by Kawachi *et al.* is withdrawn by virtue of Applicant's amendment inserting the negative limitation (not using *S. virginiae*) as taught by this piece of prior art.

Maintained - Claim Rejections - 35 U.S.C. § 102

13. Previous rejection of Claims 15 and 19-23 under 35 U.S.C. § 102(b) as being anticipated by Horinouchi *et al.* (1989) is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that because the prior art "knew" the outcome of their experiments that it does not meet the claim limitation of "the effect of said deletion on increasing said antibiotic production...being unknown...". The Examiner disagrees. The instant claim is drawn to method steps of deleting an *scbA* homolog, culturing said deletion strain, and determining

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“whether antibiotic production in said strain is increased”. The use of HH1, an afsA deletion mutant, in assays wherein streptomycin production is assayed meets all the limitations of the claimed method steps. While the preamble prescribes that antibiotic production is increased, the method steps also include methods wherein antibiotic production is not necessarily increased. In the instant case, the preamble statement is read as an intended purpose of the claimed method; such preamble statements do not limit the claimed subject matter (see M.P.E.P. § 2111.02).

Additionally, in light of the rejection under 112, second paragraph, concerning “homolog”, the Examiner notes that the specification itself calls afsA an scbA homolog yet it appears to have an entirely different function. With this in mind, the identity of scbA homologs is wholly unclear as noted above.

NEW ISSUES

Claim Objections

14. Claim 15 is objected to for improper capitalization. In line 4, “*S. Coelicolor*” should be -
--*S. coelicolor*---. Correction is required.

15. Claim 20 is objected to for being inconsistent in reference to a particular sequence. The amino acid sequence in Figure 10 is SEQ ID NO:17, which is referred to in the previous parent claim. Consistency in the claims is necessary. Correction is required. The Examiner suggests deleting “Fig. 10” in Claim 20 and substituting therefor ---SEQ ID NO:17---.

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Conclusion

16. Claims 1, 9, 11, 13, 15, and 19-23 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
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December 13, 2004